

***Remarks***

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, claims 28, 29 and 78-80 are pending in the application, with claim 28 being the sole independent claims. Claims 1-27 and 30-77 are sought to be cancelled without prejudice to or disclaimer of the subject matter therein. Amendment to claims 28, 78 and 79 is sought. The amendment to claims 28, 78 and 79 were suggested by the Examiner in the final Office Action. These amendments are believed to introduce no new matter, and place the claims into condition for allowance or better form for consideration on appeal. Hence, their entry and consideration are respectfully requested.

Based on the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

***The Office Action of December 28, 2004***

In the Office Action of December 28, 2004 (the "Office Action") claims 28, 29 and 76-79 were pending. All claims were rejected by the Examiner under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the written description requirement. Claim 79 was also objected to under 37 C.F.R. § 1.75(c) as allegedly improperly depending from claim 28, and for a minor grammatical error. The Examiner has also reasserted that the claim to priority was improper; that the amendments to the specification in the Reply of November 12, 2004, could not be entered as the directions for entering the amendments were improper. The Examiner has also clarified previous

statements made in the May 12, 2004, Office Action concerning documents cited in Applicant's Information Disclosure Statement of May 20, 2002.

***Priority***

On page 2-3 of the Office Action, the Examiner has reasserted that the present application incorrectly claims priority to U.S. Application No. 10/019,153. Applicants respectfully disagree, and again reiterate and incorporate herein comments made in the Reply of November 12, 2004. However, not in acquiescence to the Examiner's arguments but solely to advance prosecution and place the application in condition for allowance, Applicants have amended the specification in accordance with the Examiner's suggestion to make the present application a continuation of the international application. The amendment to the priority claim is supported by the previous priority claim and should not to be construed as a disclaimer of any priority claim to U.S. Application No. 10/019,153.

Applicants respectfully request that the Examiner withdraw the outstanding objection to the priority claim.

***Information Disclosure Statement***

On pages 3-4 of the Office Action, the Examiner has clarified comments made in the May 12, 2004, Office Action concerning the Information Disclosure Statement filed on May 20, 2002. On page 4, the Examiner stated:

[T]his is not an objection, it is an indication of what was and was not considered by the Examiner. The information disclosure statement did not indicate that reference AT12 was provided to fulfill the requirement for the explanation of relevance

With regards to references AP1 and AR1, the IDS was not deemed improper due to inclusion of these references. The Examiner simply indicated that the portions of these references that were considered and those portions that were not considered.

If Applicant is aware of information present in references AN2, AP1 or AR1 that is materially pertinent to the claimed subject matter, but is not evident from the English abstracts, it is Applicant's duty to bring that information to the attention of the Office.

In reply to the Examiner's comments, Applicants are *not* aware of information present in references AN2, AP1 or AR1 that is materially pertinent to the claimed subject matter, but is not evident from the English abstracts. Applicants believe that they have fully complied with the duty of disclosure under 37 C.F.R. § 1.54.

With regard to the Examiner's assertion that "[t]he information disclosure statement did not indicate that reference AT12 was provided to fulfill the requirement for the explanation of relevance," Applicants respectfully disagree and incorporate herein comments made in the previous Reply filed November 12, 2004.

Applicants' Information Disclosure Statement filed May 20, 2002 stated that:

In accordance with 37 C.F.R. § 1.98(a)(3), Applicants' undersigned representative submits the following concise statement regarding the relevance of the non-English language documents AP1, AN2 and AR1 cited on Form PTO 1449:

Document AP1, WIPO Publication No. WO 92/22644 A1, is in the French language. An unverified English language summary thereof appears on the face page of the publication.

Document AN2, European Patent Office Publication No. 0 590 530, in the name of Behringwerke Aktiengesellschaft, is in the German language. An unverified English language abstract of this publication (from Derwent WPI) is included herewith as Document AT12.

Under MPEP § 609 III (A)(3), "[s]ubmission of an English language abstract of a reference may fulfill the requirement for a concise explanation" required under 37 C.F.R. § 1.98. Therefore, the unverified English language abstract submitted as Document

AT12 is sufficient to comply with the requirements of 37 C.F.R. § 1.98, as it provides a concise explanation of the relevance of Document AN2, as understood by Applicants' representative.

***Amendments to the Specification***

On pages 4-5 of the Office Action, the Examiner has noted that the amendments to the specification could not be entered as the directions for their entry did not comply with 37 C.F.R. § 1.121. Applicants provide herein directions for entry to the amendments to the specification in accordance with the Examiner's suggestions and with 37 C.F.R. § 1.121. Entry of the amendments is respectfully requested.

***Objections to the claims***

In the Office Action at page 5, the Examiner has objected to claim 79 for recitation of a grammatical error which Applicants have now corrected by amendment and which follows the Examiner's suggestion.

The Examiner further objected to claim 79 as improperly depending from claim 28, asserting that claim 79 recites the species calcitonin which is not properly a member of the genus of peptides "not naturally occurring in milk" recited in claim 28. Following amendments to the claims, the present claim 28 does not require that the peptide be one not naturally occurring in milk. Therefore claim 79 properly depends from claim 28. Applicants request the reconsideration and withdrawal of the objection to claim 79.

***Rejections Under 35 U.S.C. § 112, First Paragraph, Written Description***

On pages 6-9 of the Office Action the Examiner has rejected claims 28, 29 and 76-80 under 35 U.S.C. § 112, first paragraph, alleging failure to comply with the written description requirement. Applicants respectfully disagree. However solely to advance prosecution and not in acquiescence to the Examiner's arguments, Applicants have cancelled claims 76 and 77, and amended claims 28, 78 and 79.

On pages 6-8 of the Office Action, the Examiner asserted that the "coding sequence operably linked to a regulatory sequence" in claim 28 and "regulatory sequence" in claims 76-78 were not supported by the specification. On page 8, the Examiner indicated that this aspect of the rejection would be overcome by cancellation of claims 76 and 77, and replacement of the term "regulatory sequence" with "promoter" in claim 78. In accordance with the Examiner's suggestion, Applicants have cancelled claims 76 and 77 and amended claim 78, thereby accommodating this portion of the rejection.

The Examiner also indicated that this aspect of the rejection of claim 28 would be overcome by replacement of the term "regulatory sequence" with the term "promoter from a gene encoding a naturally derived milk protein" in claim 28. Applicants have replaced the phrase "regulatory sequence" with "control sequence which comprises a promoter from a gene encoding a naturally-derived milk protein." Support for the term "control sequence" is found on page 20, line 23 and page 21, lines 4 to 18, and in originally filed claim 21. The specification therefore indicates that a "control sequence" enables the coding sequence to be expressed in the milk of a transgenic non-human placental animal. The paragraph on page 23 describes the components that comprise the control sequence. This paragraph suggests that the control sequence must contain a 5'

promoter sequence, derived from a naturally derived milk protein, and that it may optimally contain a 3' sequence and/or be followed by a DNA sequence directing the production of a protein leader sequence which would direct the secretion of the fusion protein across the epithelium into the milk. Thus the term "control sequence" is equivalent to the term "regulatory sequence," and there is support for the use of this term. Applicants therefore respectfully submit that this aspect of the rejection is overcome.

On pages 6 and 8 of the Office Action the Examiner has asserted that the recitation of a "peptide not naturally found in milk" in claim 28 is not supported by the specification. The Examiner indicated that the rejection would be overcome by amending claim 28 as follows: "comprises in order a first segment encoding a fusion partner protein which is lysozyme coupled in-frame to a second segment encoding a peptide other than a protein leader sequence not naturally found in milk." Applicants have amended claim 28 as suggested by the Examiner and therefore respectfully submit that this aspect of the rejection is overcome.

On pages 8 and 9 of the Office Action the Examiner has rejected claim 79 for recitation of "fragments thereof of any of (a) through (h)." Applicants have deleted this phrase from claim 79, according to the Examiner's suggestion on page 9 of the Office Action.

In view of the foregoing remarks, Applicants respectfully contend that the specification as filed fully describes the presently claimed invention. Reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph is respectfully requested.

***Conclusion***

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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